



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Marcus B. GOHLKE

Serial No.: 10/021,970

Confirmation No.: 4120

Filed: December 13, 2001

For: COMPOSITIONS CONTAINING
BETA-GLUCAN AND LACTOFERRIN
AND THEIR USE

§ Group Art Unit: 1651

§ Examiner: Susan D. Coe

§ Att'y Docket: 13479.0002.CPUS01

DECLARATION OF MARCUS B. GOHLKE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Marcus B. Gohlke, of Houston, Texas hereby declare as follows:

1. I am the named inventor on the above described patent application.
2. I have read the Final Office Action issued by Examiner Susan Coe on May 9, 2003. This Office Action indicated that claims 1, 3, and 5-18 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because applicant has not defined what times are encompassed by "an extended period of time". Claims 1, 5, and 12-14 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,406,897 B1. Claims 1, 5-11, and 16-17 were rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,296,464, U.S. Patent No. 5,783,569, and U.S. Patent No. 5,670,138.
3. The Examiner indicated that it was "difficult to assess potential unexpected results because the periods of time involved are unclear. It is not clear how long the individual

ingredients can be administered before harmful side effects are seen and it is not clear how long applicant intend to administer the combined composition.” and that “without the claims reflecting a clear period of time, it cannot be determined if the claims would be commiserate in scope with any unexpected results.”

4. As mentioned in the Response filed on February 4, 2003, the claimed compositions comprising beta-glucan and lactoferrin provide a “balanced effect”, whereby the beneficial results are obtained while reducing or eliminating the negative side effects possible from administration of either lactoferrin or beta-glucan individually.
5. I collected the following post respective reports after in depth discussion and/or consultations to evaluate the efficacy of the combined beta-glucan and lactoferrin product.
6. Ingesting beta-glucan individually has negative effects

Beta-glucan, although beneficial in increasing T helper 1 (Th-1) cells via Interleukin 12 (IL-12), also induces the body to release inflammation producing cytokines such as tumor necrosis factor alpha (TNF- α) and Interleukin 6 (IL-6). Although response time varies in individuals from a matter of hours to a number of days, sustained use of supplemental beta-glucan can produce inflammation, bloating, stiffness in the joints and general discomfort.

Post respective reports are as follows:

Example F-1: Female, age 26, exhibited cold and flu like symptoms during a full term pregnancy. In order to avoid allopathic medicines for the safety of her child, she ingested 20 milligrams of beta-glucan to enhance her immune system and to help her overcome her illness. Within two hours she experienced unusual swelling first in her right leg, then

in her left leg. She also experienced a sensation of bloating above and beyond the norm for her pregnancy. She discontinued use of the beta-glucan 'only' supplement. The next morning, with her symptoms still in full force and effect, she ingested a combination supplement containing 20 milligrams of beta-glucan and 10 milligrams of lactoferrin every two hours. By nightfall the inflammation and bloating had subsided. Additionally, she did not exhibit any cold or flu-like symptoms after two days of taking the combination supplement.

Example M-1: Male, age 45, in good health, ingested shitake and reishi mushroom residue in the form of a tea to activate his immune system in light of potential pathogen exposure. Both types of mushrooms are rich in beta-glucan. After five days of daily intake of a tea made from a combination of the mushrooms, his wrists, elbows, and shoulders were stiff and painful. After discussion with a medical doctor, a non-steroidal anti-inflammatory drug was recommended. He chose to use alternative medicine instead, and ingested a combination supplement of 20 milligrams of beta glucan and 10 milligrams of lactoferrin, taken every two hours for two days. He was able to obtain complete relief from all symptoms.

7. Ingesting lactoferrin individually has negative effects

Bovine lactoferrin ingested at the rate of 10 milligrams per day decreases TNF- α and IL-6 production eight and ten fold respectively after two weeks of lactoferrin only supplementation (Zimecki, et al. 1999). Both higher and lower amounts of lactoferrin significantly decreased both pro-inflammatory cytokines to a lesser, but still significant degree.

TNF- α is a cytokine which has the ability to modulate adipocyte metabolism, lyse tumor cells *in vitro*, and induce hemorrhagic necrosis of certain transplantable tumors *in vivo*.

Ingestion of lactoferrin alone significantly reduces these two beneficial cytokines when used for an extended period of time (i.e. after only two weeks of daily use).

Long term studies have not been completed on an organism with sustained decreases in TNF- α and IL-6 since the filing date of this patent application. One can correctly infer that long term sustained use of any supplement that decreases TNF- α will put the organism at risk. Certain prostate and other slow growing cancers could continue to grow unchecked with such a deficit and imbalance in TNF- α and/or IL-6.

8. Ingestion of beta-glucan and lactoferrin together affords beneficial results while avoiding undesirable side-effects

Compositions containing both beta-glucan and lactoferrin have been successfully tested in a number of individuals. Favorable improvements were observed, while avoiding the negative side-effects discussed above.

Post respective report is as follows:

Example M-2: Male, age 81, experienced chronic inflammation of the joints. Ingesting Ibuprofen was an integral part of his daily routine to help reduce the chronic pain caused by the inflammation. After two days of taking the combined 20 milligram beta-glucan and 10 milligram lactoferrin supplement at the rate of three times per day, he was able to discontinue use of Ibuprofen.

Example F-2: Female, age 36, suffered from chronic fatigue and fibromyalgia (CFS) and chronic inflammation. Certain CFS patients have an acute shortage of Th-1 cells and therefore can benefit from supplemental beta-glucan. She started ingesting the combined

20 milligram beta-glucan and 10 milligram lactoferrin supplement at the rate of three times per day. Within two days she felt more energetic and experienced a significant decrease in inflammation.

Example M-3: Male, age 57, depends on his feet and legs for transportation. He sprained his ankle while running an errand. He experienced inflammation in his ankles to the point of great discomfort within thirty minutes of the sprain. Upon returning home, he immediately started ingesting a combination supplement of 20 milligrams of beta-glucan and 10 milligrams of lactoferrin. He continued taking the combination supplement every hour for six hours. He experienced a marked improvement within approximately two hours. The swelling and discomfort had subsided within six hours of taking the supplement. Although his ankle was still sore the next morning, he noted a remarkable decrease in the inflammation.

Example M-4: Male, age 46, suffered from chronic inflammation in the knees as a result of extensive walking that is required as part of his job. After numerous trials with various beta-glucan only supplements (capsules containing as little as 7.5 milligrams to as much as 200 milligrams of beta-glucan only), he found that he could not ingest beta-glucan only supplements for immune support due to the increase in his inflammation. After three days of taking the combined 20 milligram beta-glucan and 10 milligram lactoferrin supplement at the rate of three times per day, he was able to enhance his immune system while reducing his inflammation and pain.

9. Conclusion

The experiences of these individuals confirm that administration of a composition comprising beta-glucan and lactoferrin provides the unexpected result of providing

sustained benefits while reducing or eliminating negative effects that would have been encountered from the administration of either component alone.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



Marcus B. Gohlke

Dated: May 7, 2004

Serial No. 10/021,970
Gohlke Declaration